PYRAMID® ANTERIOR PLATE Fixation System
Summary of Safety and Effectiveness
January 2005

I. **Company:** **Medtronic Sofamor Danek, Inc. USA**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Richard W. Treharne, PhD**
Sr. Vice President, Regulatory Affairs

II. **Proposed Proprietary Trade Name:** **PYRAMID® ANTERIOR PLATE Fixation System**

III. **Classification Name:** **Spinal Intervertebral Body Fixation Orthosis, Class II**

Regulation Number: **21 CFR Sections 888.3050**

Code: **KWQ**

IV. Product Description

The PYRAMID® ANTERIOR PLATE Fixation System consists of a variety of plates and screws, as well as ancillary products and instrument sets. The PYRAMID® ANTERIOR PLATE Fixation System implant components can be locked into a variety of configurations, with each construct being tailor-made for the individual case. The implant components are made of titanium alloy (Ti-6A1-4V) described by ASTM Standard F136 or ISO 5832-3. Stainless steel and titanium implant components must not be used together in a construct.

The Medtronic Sofamor Danek PYRAMID® ANTERIOR PLATE Fixation System is intended for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures.

The purpose of this 510(k) submission is to include modified screws to the PYRAMID® ANTERIOR PLATE Fixation System.

V. Indications

The MEDTRONIC SOFAMOR DANEK PYRAMID® ANTERIOR PLATE Fixation System is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures.
When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: 1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); 2) Pseudoarthrosis; 3) Spondylolysis; 4) Spondylolisthesis; 5)Fracture; 6) Neoplastic disease; 7) Unsuccessful previous fusion surgery; 8) Lordotic deformities of the spine; 9) Idiopathic thoracolumbar or lumbar scoliosis; 10) Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida,

or myelomenigocele; and/or 11) Neuromuscular deformity (i.e., scoliosis, lordosis, and / or kyphosis) associated with pelvic obliquity.

VI. Substantial Equivalence

Documentation was provided which demonstrated the PYRAMID® ANTERIOR PLATE Fixation System to be substantially equivalent to the PYRAMID® ANTERIOR PLATE Fixation System components previously cleared in K013665.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2005

Richard W. Treharne, Ph.D.
Vice President Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K050117
Trade Name: PYRAMID™ Anterior Plate Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: January 14, 2005
Received: January 18, 2005

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K050117

Device Name: PYRAMID® ANTERIOR PLATE Fixation System

Indications for Use

The MEDTRONIC SOFAMOR DANEK PYRAMID® ANTERIOR PLATE Fixation System is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures.

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Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050117